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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,753	07/13/2001	Robert T. Lyons	D-2973	3325
33197	7590	02/26/2004	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618			WAX, ROBERT A	
		ART UNIT	PAPER NUMBER	
		1653		

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/904,753	LYONS, ROBERT T.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 28 November 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 81-120 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 81-120 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 88-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 88 recites "said component is a sole preservative". If the magainin is the only preservative the word "a" should be "the".

### ***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 81-86 and 106-112 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tusé et al.

Tusé et al. teach self-preserving ophthalmic solutions comprising indolicidins as the primary therapeutic agent. Other ingredients are discussed at column 14, line 49 – column 19, line 13. they include buffers, tonicity adjusting agent, surfactants where the

solution is to be used for lens cleaning, chelating agent for some embodiments, divalent cations in certain preferred embodiments, bacteriostatic adjuvant such as magainin (column 17, line 51) and mixtures of bacteriostatic adjuvants. At column 19, lines 11-13 they discuss the addition of various medicinal agents such as antibiotics for treatment of eye infection. These teachings clearly anticipate the above claims, which now emphasize that the magainin preservative is not the only therapeutically effective agent in the composition.

5. Claims 88-94 and 101-117 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Maloy.

Maloy teaches an ophthalmic composition that is applied topically onto the eye (col. 29, lines 27-28 and col. 30, lines 53-55) (present claim 106) comprising a sole preservative (col. 28, lines 48-50 and claim 3), namely, therapeutically effective amount of a magainin antimicrobial peptide identical to SEQ ID No: 4 (Maloy's SEQ ID No: 2 and col. 31, line 56) in a distilled water solution which also may serve as a tonicity component (col. 32 line 14) (present claims 91, 104, 110 and 116). At column 28, lines 48-50 Maloy specifically discusses the use of the magainin mimetics as preservatives. These teachings clearly anticipate the above claims.

***Claim Rejections - 35 USC § 103***

6. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tusé et al. in view of Maloy.

The teachings of the references are outlined above. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the magainin mimetic of Maloy for magainin itself in the composition of Tusé et al. with the expectation of achieving the beneficial results taught by Maloy.

7. Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tusé et al. in view of Ding et al.

Ding et al. teach an ophthalmic composition in the form of an oil-in-water emulsion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the composition of Tusé et al. as an emulsion in order to gain the advantages taught by Ding et al.

8. Claims 88-94 and 101-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maloy in view of Huth et al.

The teachings of Maloy have been outlined above.

Huth et al. discuss the differences between disinfecting contact lens compositions and preserved contact lens care compositions. These teachings confirm what is very well known in this art, that is, that a larger amount of an antibacterial agent

is used to disinfect but a lower amount is effective to preserve. Another term of art for preservative in this context is "bacteriostatic agent".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the magainin mimetic of Maloy as a preservative in view of the teachings of Huth et al. to the effect that the same agents that kill bacteria also prevent their reinfecting the solution. The purpose of this rejection is to reinforce the rejection over Maloy alone; Huth et al. provides verification for Maloy's statement that the magainin mimetic may be used as preservatives.

9. Claims 95-100 and 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maloy in view of Huth et al. as applied to claims 88-94 and 101-117 above, and further in view of Ding et al.

The teachings of the references have been outlined above. It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the composition of Maloy as an emulsion in order to achieve the beneficial results taught by Ding et al.

10. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maloy in view of Huth et al. as applied to claims 88-94 and 101-117 above, and further in view of Ripley et al.

Ripley et al. teach the conventionality of using preserved ophthalmic solutions as surgical irrigants, see column 1, lines 49-62.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Maloy as a surgical irrigant with the expectation of beneficial results as taught by Ripley et al.

***Response to Arguments***

11. Applicant's arguments filed November 28, 2003 have been fully considered but most of them are not persuasive.

Applicants' arguments and amendments regarding the SEQ ID Nos. and trademarks are persuasive, as are the arguments regarding the previous rejection under 35 USC 112, second paragraph.

Applicants argue that Huth et al. do not specifically disclose the present invention. Examiner does not agree with each point made but now that the presence of an additional component besides the magainin has been emphasized it is clear that Huth et al. do not anticipate the claims.

Applicants next argue that Hunt does not specifically disclose the present invention either. Examiner does not agree with each point made but, now that the presence of an additional component besides the magainin has been emphasized, it is clear that Hunt does not anticipate the claims.

Applicants further argue that Maloy does not disclose, teach or suggest the present invention. Examiner must respectfully disagree, hence the above rejection under 35 USC 102(b). Maloy does indeed disclose ophthalmic compositions comprising

a magainin antimicrobial protein as a preservative. The exact teaching appears at column 28, lines 48-50 where it states, "Because of the antibiotic properties of the peptides, they may also be used as preservatives . . . of materials susceptible to microbial contamination." This specifically contradicts Applicants' argument. The next argument revolves around the teaching of Maloy that the magainin mimetic is the sole preservative in the composition. Example 1 provides a composition wherein magainin mimetic is the sole preservative; attention is also directed to claim 6 which recites a pharmaceutical composition comprising the compound of claim 4 and an acceptable pharmaceutical carrier. Again, this specifically contradicts applicants' arguments.

Applicants next argue that Maloy do not teach one of skill in the art to apply the compositions to the eyes, even in view of Maloy's teaching that the magainin mimetics are useful in treatment of eye infections. While some eye infections may be treated by systemic administration of an antibiotic, the vast majority of such treatments are by direct instillation into the eye in the form of drops or some other liquid. While the level of proof is not clear on this point, anyone who has treated a child for "pink eye" (conjunctivitis) knows full well that the treatment is via eye drops. Thus, applicants' arguments against the anticipation of the above claims by Maloy are not persuasive.

Applicants next argue that Deckers et al. do not disclose, teach or suggest the present invention. Examiner agrees that, although eye makeup removers are used near the eyes, they do not constitute ophthalmic solutions and that Deckers et al. do not anticipate the claims.

Applicants next argue that to combine the teachings of Maloy and/or Hunt with those of Stevenson would require hindsight. While not agreeing with this argument, Examiner withdraws the rejections involving Stevenson.

Applicants' final argument is that there is no motivation to combine Maloy and Kross for any reason whatsoever. Examiner does not agree with this analysis, but in any event, withdraws the rejection over Maloy in view of Kross. A new rejection of claim 107 is made over Maloy in view of Ripley et al.

The instant Office action is made nonfinal since, even though the aspect of the presence of a therapeutic agent besides the magainin or magainin mimetic was not clear before, the claims did in fact require one or more such additional components.

### ***Conclusion***

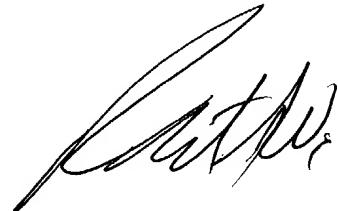
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax  
Primary Examiner  
Art Unit 1653